K131036

510(k) Summary

JUL 1 2 2013

510(k) Owner

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April 1, 2013

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Device Classification

510(k) Name: Yamahachi Denture Base Resins
Trade/Model Names: Basis, Basis HI, Basis Twin Cure, Basis Flow, Re-Fine Bright
Common Name: Denture Base Polymer
Classification Name: Denture Relining, Repairing, or Rebasing Resin
Regulation Number: 872.3760
Product Code: EBI
Regulatory Class: II

Predicates

K102874 Veracril, Veracril HI, Ez-Cryl (New Stetic, Columbia)
K102640 Vertex Self-Curing, Vertex Castavaria (Vertex Dental, The Netherlands)

Intended Use

Yamahachi Denture Base Resins is a system of heat- and self-cure acrylic polymers intended for fabrication or repair of the denture base.

Device Description

Yamahachi Denture Base Resins is supplied in powder and liquid form. The powder is primarily a polymer of polymethyl methacrylate (PMMA) beads with small quantities of initiator and color pigments. The liquid is primarily the monomer methyl methacrylate (MMA) with small quantities of a cross-linking agent and activator.

To fabricate the denture base, the powder and liquid materials are mixed together and stirred to create a dough state that is packed or poured into a mold, saddle, or core. The resin then cures either through heat application (water bath, rapid immersion, or microwave oven) or a self-curing process (pressure vessel or via quick-setting).

While heat-cure resins are generally used to fabricate denture bases, self-cure acrylics are most often indicated for repair and relining of the dentures. The subject device includes three heat-cure resins (Basis, Basis HI, and Basis Twin Cure) and two self-cure resins (Basis Flow and Re-Fine Bright).

Device Comparison To Predicates

A comparison of technological characteristics between the subject and predicate devices follows in Tables 5A and 5B...

Table 5A -- Comparison Of Heat-Cure Acrylics

	Subject Devices	Predicate Devices	Differences
Device Names	**Basis, Basis HI, Basis Twin Cure**	**Veracril, Veracril HI, EZ-cryl**	**NA**
Manufacturer	Yamahachi Dental (Japan)	New Stetic (Columbia)	NA
510(k)	Not assigned yet	K102874 (Bundle of 5 Heat-Curing & 3 Self-Curing)	NA
Classification & Product Code	872.3760; EBI	872.3760; EBI	No difference in Device Description or Intended Use
Device Description	Traditional heat-cure & microwave-cure acrylic resin for total or partial denture base and for removable prosthesis	Denture system consisting of monomer and polymer powder and liquid components (traditional heat-cured & microwave-cured acrylic resin for total or partial denture base and for removable prosthesis)	

Intended Use	Repair or fabrication of denture base	Repair or fabrication of denture base	
Product State	Polymer powder & monomer liquid	Polymer powder & monomer liquid	The only difference in Method Of Use is determination of mixing ratio. This difference is related to characteristics of polymer particle size, but does not affect performance of device nor raise issues of safety or effectiveness, a conclusion supported by meeting requirements of standard ISO 20795-1.
Mixing Ratio (Powder:Liquid)	100g:43ml (Basis & Basis HI); 100g:40ml (Basis Twin Cure)	2:1 by weight or 3:1 by volume	
Mixing Time	30 sec	30 sec	
Pressing Technique	Pack dough in plaster model, apply pressure, trim excess, apply final pressure (10 - 15 minute packing time)	Pack dough in flask, apply pressure, trim excess, apply final pressure	
Application Time	30 minutes	Approx 10 minutes	
Polymerization (Curing) Method	Water Bath: Immerse flask in water & slowly raise to boiling over 30 min, boil 30 - 40 min, air cool 30 min (Basis & Basis HI); Rapid Curing: Immerse flask in boiling water 30 min (Basis TC); Microwave: Put flask in MWO 500W for 3 min, air cool 30 min (Basis TC)	Water Bath: 90 min at 73° C, 30 min boiling, 30 min air cool, 15 min water cool (Veracril devices); Microwave: 10 min in 3 stages in MWO, air cool 30 min, 15 min water cool (EZ-cryl only)	
Components (See legend after table)	Powder: PMMA, MMA (Basis Hi), initiator, pigments; Liquid: MMA, crosslinker, activator (Basis TC)	Powder: PMMA, pigments; Liquid: MMA, crosslinker	The only difference in Product Components are minor variances in percentages of ingredients, which do not affect product performance, safety, or effectiveness, as supported by meeting the standards of ISO 20795-1.
Standards of Conformity	ISP 9001:2008; ISO 13485:2003; MDD (93/42/EEC); ISO 14971	ISP 9001:2008; ISO 13485:2003	All Physical Properties within specification
Biocompatibility	ISO 10993-1, ISO 7405	ISO 10993-1, ISO 7405	
Physical Properties	ISO 20795-1	ANSI/ADA 12:2002; ISO 1567:1999	
Flexural Strength (65 MPa Minimum)	Basis: 84.3 MPa; Basis HI: 87 MPa; Basis Twin Cure: 81.0 MPa	Veracril: 70.8 MPa; Veracril HI: 88.1 MPa; Ez-cryl: 70.5 MPa	
Flexural Modulus (2,000 MPa Min)	Basis: 2,067 MPa; Basis HI: 2,178 MPa; Basis Twin Cure: 2,299 MPa	Veracril: 5,300 MPa; Veracril HI: 5,804 MPa; Ez-cryl: 5,700 MPa	
Impact-Resistance (Min 1.9 MPa m1/2)	Basis/Basis TC: Not Applicable; Basis HI: > 2.26 MPa $m^{1/2}$	Veracril/Ez-cryl: Not Applicable; Veracril High Impact: 3.1 MPa $m^{1/2}$	

Residual Monomer (Maximum 2.2%)	Basis: 0.4%; Basis HI: 0.7%; Basis Twin Cure: 0.2%	Veracril: 0.98%; Veracril HI: 1.88%; Ez-cryl: 0.80%	
Sorption (Max 32 ug/mm3)	Basis: 10.7 ug/mm^3; Basis HI: 22.8 ug/mm^3; Basis Twin Cure: 22.4 ug/mm^3	Veracril: 18.1 ug/mm^3; Veracril HI: 14.5 ug/mm^3; Ez-cryl: 19.1 ug/mm^3	
Solubility (Max 1.6 ug/mm3)	Basis: 0.6 ug/mm^3; Basis HI: 0.4 ug/mm^3; Basis Twin Cure: 0.2 ug/mm^3	Veracril: 0.8 ug/mm^3; Veracril HI: 0.9 ug/mm^3; Ez-cryl: 0.72 ug/mm^3	
Classification (ISO 20795-1:2008)	Basis & Basis HI: Type 1 Class 1; Basis Twin Cure: Type 5	Veracril & Veracril HI: Type 1 Class 1; EZ-cryl: Type 5	No Classification difference

MMA - Methyl-methacrylate

PMMA - Poly-methyl-methacrylate

PEMA - 2-(N-pyrolyl) ethyl methacrylate

Table 5B -- Comparison Of Self-Cure Acrylics

	Subject Devices	Predicate Devices	Differences
Device Names	**Basis Flow, Re-Fine Bright**	**Vertex Self Curing, Vertex Castavaria**	**NA**
Manufacturer	Yamahachi Dental (Japan)	Vertex-Dental (Netherlands)	NA
510(k)	Not assigned yet	K102640 (Bundle of 3 Self-Curing Resins)	NA
Classification & Product Code	872.3760; EBI	872.3760; EBI	No difference in Device Description or Intended Use
Device Description	Basis Flow: Self-curing denture base material intended as a pouring and repair acrylic. Re-fine Bright: Multifunctional self-polymerizing denture base material for repair and relining of full & partial dentures	Vertex Self Curing: Self-curing denture base material intended as a pouring and repair acrylic. Vertex Castavaria: Multifunctional self-polymerizing denture base material for repair and relining of full & partial dentures	
Intended Use	Repair and relining of full & partial dentures	Fabrication, repair and relining of full & partial dentures	

Product State	Polymer powder & monomer liquid	Polymer powder & monomer liquid	The only difference in Method Of Use is curing method for Re-Fine Bright, which is not pressure cured. This difference does not affect performance of device, safety, or effectiveness, as supported by meeting requirements of standard ISO 20795-1.
Mixing Ratio (Powder:Liquid)	100 g : 50 - 60 ml	100 g : 60 ml	
Mixing Time	5 - 30 sec	20 sec	
Dough Time	Max 3 min	Max 4.5 - 8 min	
Working Time	Max 4 min	Max 5 - 8 min	
Polymerization (Curing) Method	Basis Flow: 30 min at 55° C in 0.2 atm pressure vessel, air cool 30 min; Re-Fine Bright: Let hard polymerize	Vertex Self Curing: 10 min at 55° C in 2.5 bar pressure vessel; Vertex Castavaria: 30 min at 55° C in 2.5 bar pressure vessel	
Components (See legend before table)	Powder: PMMA, PEMA, activators, pigments; Liquid (Basis Flow): MMA, crosslinker, activator; Liquid (Re-fine Bright): MMA, crosslinker, activators	Powder: PMMA 99.1%, Inhibitor (dibenzoyl peroxide) <1%; Liquid: MMA >95%, Crosslinker <5%, Accelerators <1%, UV Absorber <<1%	The only difference in Product Components are minor variances in percentages of ingredients, which do not affect product performance, safety, or effectiveness, as supported by meeting the standards of ISO 20795-1.
Standards of Conformity	ISP 9001:2008; ISO 13485:2003; MDD (93/42/EEC); ISO 14971	ISO 1567, ISO 179-1, ASTIM F 895-84	All Physical Properties within specification
Biocompatibility	ISO 10993-1, ISO 7405	ISO 7405	
Physical Properties	ISO 20795-1	ISO 20795-1	
Flexural Strength (60 MPa Minimum)	Basis Flow: 80.1 MPa; Re-Fine Bright: 73.8 MPa	Vertex Self Curing: 68 MPa; Vertex Castavaria: 79MPa	
Flexural Modulus (1,500 MPa Min)	Basis Flow: 1,657 MPa; Re-Fine Bright: 1,529 MPa	Vertex Self Curing: 2,028 MPa; Vertex Castavaria: 2,316 MPa	
Residual Monomer (Maximum 4.5%)	Basis Flow: 4.2%; Re-Fine Bright: 3.3%	Vertex Self Curing: 3.76%; Vertex Castavaria: 3.91%	
Sorption (Max 32 ug/mm3)	Basis Flow: 18.8 ug/mm^3; Re-Fine Bright: 15.8 ug/mm^3	Vertex Self Cure: 20.3 ug/mm^3; Vertex Castavaria: 23.2 ug/mm^3	
Solubility (Max 8.0 ug/mm3)	Basis Flow: 1.8 ug/mm^3; Re-Fine Bright: 2.3 ug/mm^3	Vertex Self Cure: 1.8 ug/mm^3; Vertex Castavaria: 1.8 ug/mm^3	
Classification (ISO 20795-1:2008)	Basis Flow: Type 2 Class 2; Re-Fine Bright: Type 2 Class 1	Vertex SC: Type 2 Class 2; Vertex Castavaria: Type 2 Class 1	No Classification difference

Non-Clinical Tests

Bench tests were performed on the subject device in conformity with ISO 20795-1. These tests confirmed the different resins (Basis, Basis HI, Basis Twin Cure, Basis Flow, and Re-Fine Bright) all met the performance criteria established by that standard.

Substantial Equivalence Discussion

As noted above...

- Product Description and Intended Use are the same for the subject and predicate devices.
- The only difference in Method Of Use is determination of mixing ratio. This difference is related to characteristics of polymer particle size, but does not affect performance of device nor raise issues of safety or effectiveness, a conclusion supported by meeting requirements of standard ISO 20795-1.
- The only difference in Product Components are minor variances in percentages of ingredients, which do not affect product performance, safety, or effectiveness, as supported by meeting the standards of ISO 20795-1.
- The Physical Properties of both the subject and predicate devices conform to the standards of ISO 20795-1.
- Classification of the dental acrylic resins is the same between subject and predicate devices.

Yamahachi Denture Base Resins has the same intended use as the predicates. The subject device also has minor differences in technological characteristics that could not affect safety or effectiveness. Bench tests show conformance with performance standards in ISO 20795-1:2008 for all five models included in this submission (Basis, Basis HI, Basis Twin Cure, Basis Flow, and Re-fine Bright).

In conclusion, Yamahachi Denture Base Resins warrants a finding of substantial equivalence to legally marketed devices from New Stetic (Columbia) and Vertex Dental (The Netherlands) and of proper clearance for premarketing activities in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 12, 2013

Yamahachi Dental Manufacturing Co.
C/O Mr. Claude Berthoin, President
Denterprise International, Inc.
110 E. Granada Boulevard, Suite 207
Ormond Beach, FL 32176

Re: K131036
Trade/Device Name: Yamahachi Denture Base Resins
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Repairing Resin
Regulatory Class: II
Product Code: EBI
Dated: April 26, 2013
Received: April 29, 2013

Dear Mr. Berthoin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Applicant: Yamahachi Dental Manufacturing Co.

510(k) Number (if known): K131036

Device Name: Yamahachi Denture Base Resins

Indications For Use:

Yamahachi Denture Base Resins is intended for fabrication or repair of the denture base.

All devices are sold by or on the order of a physician. They are not for use by the general public or over-the-counter.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE).

Division Sign-Off
Office of Device Evaluation

510(k)_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K131036